mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1670 Neon gas analyzer.

(a) *Identification.* A neon gas analyzer is a device intended to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

§ 868.1690 Nitrogen gas analyzer.

(a) *Identification.* A nitrogen gas analyzer is a device intended to measure the concentration of nitrogen in respiratory gases to aid in determining a patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1700 Nitrous oxide gas analyzer.

(a) *Identification.* A nitrous oxide gas analyzer is a device intended to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1720 Oxygen gas analyzer.

(a) *Identification.* An oxygen gas analyzer is a device intended to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polarography, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

(b) *Classification.* Class II (performance standards).

§ 868.1730 Oxygen uptake computer.

(a) *Identification.* An oxygen uptake computer is a device intended to compute the amount of oxygen consumed by a patient and may include components for determining expired gas volume and composition.

(b) *Classification.* Class II (performance standards).

§ 868.1750 Pressure plethysmograph.

(a) *Identification.* A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

(b) *Classification.* Class II (performance standards).

§ 868.1760 Volume plethysmograph.

(a) *Identification.* A volume plethysmograph is an airtight box, in which a patient sits, that is used to determine the patient's lung volume changes.

(b) *Classification.* Class II (performance standards).

§ 868.1780 Inspiratory airway pressure meter.

(a) *Identification.* An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

(b) *Classification.* Class II (performance standards).

§ 868.1800 Rhinoanemometer.

(a) *Identification.* A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

(b) *Classification.* Class II (performance standards).

§ 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.

(b) *Classification.* Class II (performance standards).

§ 868.1850 Monitoring spirometer.

(a) *Identification.* A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

(b) *Classification.* Class II (performance standards).

§ 868.1860 Peak-flow meter for spirometry.

(a) *Identification.* A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

(b) *Classification.* Class II (performance standards).

§ 868.1870 Gas volume calibrator.

(a) *Identification.* A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the output of gas volume measurement instruments by delivering a known gas volume.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 868.1880 Pulmonary-function data calculator.

(a) *Identification.* A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

(b) *Classification.* Class II (performance standards).

§ 868.1890 Predictive pulmonary-function value calculator.

(a) *Identification.* A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

(b) *Classification.* Class II (performance standards).

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) *Identification.* A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.

(b) *Classification.* Class II (performance standards).

§ 868.1910 Esophageal stethoscope.

(a) *Identification.* An esophageal stethoscope is a nonpowered device that is inserted into a patient's esophagus to enable the user to listen to heart and breath sounds.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.1920 Esophageal stethoscope with electrical conductors.

(a) *Identification.* An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to a patient's heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

(b) *Classification.* Class II (performance standards).

§ 868.1930 Stethoscope head.

(a) *Identification.* A stethoscope head is a weighted chest piece used during anesthesia to listen to a patient's heart, breath, and other physiological sounds.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989]

§ 868.1965 Switching valve (ploss).

(a) *Identification.* A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen only to a patient's heart or korotkoff (blood pressure) sounds through the other channel.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of